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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
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ART UNIT	PAPER NUMBER
1627	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/552,231	STANIFORTH ET AL.
	Examiner	Art Unit
	SAMIRA JEAN-LOUIS	1627

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 May 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-10,13-18,21-35 and 42-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-10,13-18,21-35 and 42-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09/08/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continuation Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/03/2010 has been entered.

Response to Arguments

This Office Action is in response to the amendment submitted on 05/03/2010. Claims 1-2, 4-10, 13-18, 21-35, and 42-47 are currently pending in the application, with claims 3, 11-12, 19-20, and 36-41 having being cancelled. Accordingly, claims 1-2, 4-10, 13-18, 21-35, and 42-47 are being examined on the merits herein.

Receipt of the aforementioned amended claims is acknowledged and has been entered.

Applicant's argument with respect to the Obviousness Double Patenting (ODP) rejection over co-pending application 10/621,964 has been fully considered. Given that co-pending application 10/621,964 is now abandoned, such rejection is now moot.

Consequently, the ODP rejection over claims 1, 11, 16, and 30-33 of co-pending application 10/621,964 is hereby withdrawn.

Applicant's argument with respect to the 103(a) rejection over Gupta in view of Lucas et al. has been fully considered. Applicant argues that the presently claimed invention achieves unexpected results and is unexpected. Particularly, applicant argues that the instant claimed invention recites the provision that Cmax is achieved within 1 to 5 minutes of administration (i.e. Tmax is 1-5 min.) while also avoiding side effects. Such arguments are however not found persuasive as the examiner contends that the results achieved by the instant invention are neither unpredictable nor unexpected. While Gupta is silent to the Tmax achieved with inhaled dosages, the Examiner contends that Gupta teaches the exact same composition of apomorphine as the instant invention and for the same purpose (see abstract and pg. 1, paragraph 0011-0014). Additionally, Gupta teaches that the composition can be administered via inhalation and Gupta further teaches that a therapeutically effective amount of apomorphine can be administered and that less than 15% of the patients treated experienced emesis (i.e. a type of side effect). As a result, the Examiner maintains that one of ordinary skill in the art would have found it obvious to administer the apomorphine within the effective dosage range including the dosage range of 200-1200 micrograms. One of ordinary skill would have optimized the proper dosage range for inhalation administration and determine the most effective dosage amount to administer during routine experimentation and would have arrived at applicant's claimed dosage. Moreover,

attention is directed to Jenkins et al. who teach that administration of drugs via the pulmonary route (i.e. inhalation) provides several advantages including rapid transport into the blood and that such particles must possess a particular size depending on where in the lungs such drugs are desired for deposition (see section 3.1.1.1.2, pulmonary). As a result, the Examiner maintains that achieving a Tmax between 1 and 5 minutes is neither unpredictable nor unexpected as one skilled in the art who follows the teachings of Gupta and that of the prior art on pulmonary administration would have obtained the exact same dosages and Tmax as the instant invention.

While applicant argues that the dosage of Gupta between 3-12 mg is different from the instant invention, the Examiner reminds applicant that such dosage range was given in the form of tablets for sublingual administration (see pg. 7, paragraph 074). Moreover, Gupta teaches that changes can be made in the composition and thus such composition can vary (see pg. 7, paragraphs 0076-0077). Consequently, the Examiner maintains that one skilled in the art would have found it obvious to optimize the dosage range of apomorphine for inhalation administration and would have achieve similar dosage amounts and Tmax as the instant invention.

Applicant's argument with respect to the press release (i.e. Annex 1 and 2) which supports applicant's argument that the Tmax is not predictable by one skilled in the art has again been fully considered. Such arguments are however not found persuasive as the press release was not submitted in the response to Arguments. Nonetheless, the examiner maintains that given Gupta teaches the use of apomorphine via inhalation at

effective amount for treatment of sexual dysfunction and given that the prior art teaches that inhalation would result in rapid release into the blood, one of ordinary skill would have indeed found it obvious to optimize the dosage range and would have arrived at applicant's invention. As for Lucas, such reference was provided to demonstrate that pulmonary delivery requires mass median aerodynamic diameters in the range of 1-5 microns and that excipient inclusion is helpful for bulk properties (see Lucas, pg. 1643, abstract; pg. 1644, right col., and pg. 1646, right col.). Vervaet, on the other hand, was provided to demonstrate that inhalation composition can be made as pMDI formulation and can further include water or other solvents and a propellant.

As for Pierre, it was provided to demonstrate that various types of dry powder inhaler devices are in existence and thus the composition of Gupta is obvious to formulate into various forms.

For the foregoing reasons, the ODP rejection is withdrawn. However, the 103(a) rejections were indeed proper. However, in view of applicant's amendment, the following ODP and 103 (a) Non-Final rejections are being made.

Provisional Non-Statutory Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent

and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 42, and 44 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 19-20 of copending Application No. 10/552,326 (hereinafter Staniforth US Patent Application No.

‘964). Although the conflicting claims are not completely identical, they are not patentably distinct from each other because both applications are directed to a dry powder breath actuated inhaler device containing a composition comprising apomorphine or its pharmaceutically acceptable salt or ester. The claimed invention and co-pending application Staniforth ‘326 are rendered obvious over another as the claimed invention teaches a device with a broad genus of composition for pulmonary inhalation comprising apomorphine, its pharmaceutically acceptable salt or ester wherein the apomorphine has a mass median aerodynamic diameter (MMAD) of 10 µm or less whereas Staniforth ‘326 teaches a device comprising a subgenus of a composition comprising apomorphine and a metal stearate wherein the MMAD is no more than 10 µm. While the instant invention does not recite the use metal stearate, the term "comprising" in the instant claims does not exclude addition of other components and thus is rendered obvious by co-pending application’326. Thus, the aforementioned claims of the instant application are substantially overlapping in scope as discussed hereinabove and are prima facie obvious over the cited claims of corresponding application No. 10/552,326.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-2, 4-10, 13-18, 21-28, and 42 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Gupta et al. (U.S. 2002/0006933 A1, previously cited) in view of Jenkins et al. (Pharmacokinetics: Drug, Absorption, Distribution, and Elimination, 1998, Chapter 3, pgs. 1-51.) and in further view of Lucas et al. (Pharmaceutical Research 1999, Vol. 16, No. 10, pgs. 1643-1647, previously cited).

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

It is respectfully pointed out that the recitation "for treating sexual dysfunction by pulmonary inhalation" has not been given patentable weight because the recitation occurs in the preamble of a product claim. A preamble of a product claim is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See In re Hirao, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and Kropa v. Robbie, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Gupta et al. teach a method for administering apomorphine to a patient for the treatment of sexual dysfunction while reducing undesirable side effects and wherein the apomorphine is attained with the patient's plasma of up to 10 ng/ml (see abstract and pg.1, paragraphs 0001 and 0011-0012). Gupta et al. further teach that the method of administration can be by inhalation to the lungs (see pg. 1, paragraphs 0012 and 0020 and pg. 2, paragraph 0033). Additionally, Gupta et al. disclose that the method may be utilized to treat sexual dysfunction in males or females and that the plasma concentration of apomorphine (i.e. Cmax) may be from about 0.1 to about 7 ng/ml (instant claims 4-5; see pg. 2, paragraph 0023). Gupta et al. further teach that the method can treat impotence or erectile dysfunction (instant claim 15) in males which can result from psychological disturbances (i.e. psychogenic; instant claim 17), physiological abnormalities in general (i.e. organic; instant claim 18), or for female sexual dysfunction (instant claim 16; see pg. 2, paragraphs 0037 and 0039-0040).

Powders of apomorphine can also be used and placed in a capsule wherein the capsule is set in an inhalation device (instant claim 42; see pg. 3, paragraph 0047). The delivery device for inhalation may also include metered dose inhalers, dry powder inhalers or nebulization of solution or suspension (instant claims 19 and 42; see pg. 2, paragraph 0035). Apomorphine can exist as a free base or as an acid addition salt including the hydrochloride salt (instant claim 2; see pg. 3, paragraphs 0042-0043). Importantly, Gupta et al. teach that the apomorphine and its pharmaceutically acceptable salts thereof may be formulated into compositions together with one or more non-toxic physiologically tolerable or acceptable diluents, carriers, adjuvants or vehicle (instant claim 1; see pg. 3, paragraph 0048). Of interest, Gupta et al. teach addition of adjuvants such as lecithin for maintaining proper fluidity (instant claims 24 and 26; see pg. 4, paragraph 0054). For solid dosage forms, powders may be formulated wherein the active compound may be mixed with at least one inert, pharmaceutically acceptable excipient or carrier including fillers such as lactose or lubricants such as magnesium stearate (instant claim 27; see pg. 4, paragraph 0055). Gupta et al. further demonstrated dose proportionate increase in both Cmax and in AUC (instant claims 7-9) and that administration by inhalation results in a more effective bioavailability without a proportional increase in adverse side effects (instant claim 10; see pg. 6, paragraph 0069). For the inhalation studies, Gupta teaches the use of 0.5 mg, 1mg, and 2 mg dosage amount that was administered to dogs and found a Tmax of 0.17 h along with high bioavailability and low side effects (see pg. 5, paragraph 0069).

Gupta et al. do not specifically teach a composition wherein the composition provides a nominal dose of from 200 to about 1200 micrograms and wherein the Cmax is achieved within 1 to 5 minutes or a terminal half-life of between 50 and 70 minutes or the exact dosages of apomorphine or additives in the composition. Similarly, Gupta et al. do not teach that apomorphine has a mass median aerodynamic diameter of 10 microns or less.

Jenkins et al. teach that administration of drugs via the pulmonary route (i.e. inhalation) provides several advantages including rapid transport into the blood and that such particles must possess a particular size depending on where in the lungs such drugs are desired for deposition (see section 3.1.1.1.2, pulmonary). As a result, the Examiner maintains that achieving a Tmax between 1 and 5 minutes is neither unpredictable nor unexpected as one skilled in the art who follows the teachings of Gupta and that of the prior art on pulmonary administration would have obtained the exact same dosages and Tmax as the instant invention.

Gupta et al. also teach that the composition can vary and thus such variation would inevitably result in a Cmax of within 1 to 5 minutes. Consequently, the Examiner maintains that one skilled in the art would have found it obvious to optimize the dosage range of apomorphine for inhalation administration and would have achieve similar dosage amounts and Tmax as the instant invention.

Moreover, the Examiner maintains that adjusting the concentration of apomorphine is well within the purview of the skilled artisan and determination of the most effective dosage of apomorphine in humans would be well within the purview of the skilled artisan depending upon the severity of the disease, the form of the dosage, or the patient to be treated.

As for the terminal half-life, the Examiner contends that one of ordinary skill in the art would have found it obvious to optimize the dosage so as to obtain the best half-life of a dosage that is effective in treating sexual dysfunction.

Lucas et al. teach that an effective and efficient dry powder system for pulmonary delivery requires particles of mass median aerodynamic diameters that are in the range of 1.0-5 microns (see pg. 1643, abstract). For deep lung regions, even smaller aerodynamic diameters are preferred in the range of 1-2.0 microns (see pg. 1643, abstract). Importantly, Lucas et al. teach that dry powder inhalers (DPI) relies on both the formation of ordered units between the drug and the coarse carrier however efficiency is often poor (see pg. 1643, abstract). Thus, Lucas et al. teach that to avert the problems with poor flow, several solutions can be used including inclusion of excipient such as L-leucine which modifies the bulk properties of the formulation (see pg. 1643, abstract and pg. 1644, right col. and pg. 1646, right col.). For Preparation of powder aerosol formulation, Lucas et al. teach the use of an active such as salbutamol

sulphate using either a coarse or fine particles of lactose of 63-90 microns (instant claim 28; see pg. 1644, left col.).

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious to optimize the dosage and administer the composition of Gupta for the treatment of sexual dysfunction and expect that such dosage would have possessed a Tmax of 1 to 5 min given that Jenkins et al. teach that administration via pulmonary route normally results in rapid transport into the blood. Consequently, determining the effective dosage of apomorphine to be administered via inhalation would lead one skilled in the art to a composition that results in a Cmax within 1 to 5 minutes. Thus, given the teachings of Gupta, Jenkins, and Lucas, one of ordinary skill would have been motivated to utilize the composition of Gupta and optimize the dosage of apomorphine and additives as taught by Lucas with the reasonable expectation of providing a composition that is effective in rapidly treating sexual dysfunction and composition that achieves high plasma levels.

While the exact dosages of the ingredients are not disclosed by Gupta et al., it is generally noted that differences in concentration do not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or dosage is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA

1955). Given that applicant did not point out the criticality of specific ranges or dosages of the invention by comparing inhalation forms of the composition (as opposed to sublingual vs. inhalation of the instant invention), it is concluded that the normal desire of scientists or artisans to improve upon what is already generally known would provide the motivation to determine where in a disclosed set of ranges is the optimum range of dosages.

Claims 29-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gupta et al. (U.S. 2002/0006933 A1, previously cited) in view of Jenkins et al. (Pharmacokinetics: Drug, Absorption, Distribution, and Elimination, 1998, Chapter 3, pgs. 1-51.) and in further view of Lucas et al. (Pharmaceutical Research 1999, Vol. 16, No. 10, pgs. 1643-1647, previously cited) as applied to 1-2, 4-10, 13-18, 21-28, and 42 above and in further view of Vervaet et al. (International Journal of Pharmaceutics. 1999, Vol. 186, pgs. 13-30, previously cited).

The Gupta reference is as discussed above and incorporated by reference herein. However, Gupta does not teach a composition comprising a pMDI formulation with a propellant, water, and a solvent.

Vervaet et al. teach the current use of HFA 134 a and HFA 227 (instant claim 29-30 and 33-34) in pressurized metered dose inhalers (pMDI) along with co-solvents such as ethanol (pg. 21, left col.; instant claims 29 and 31) and surfactants and that the

aforementioned propellants and excipients are particularly useful in stabilizing such suspensions and in enhancing the solubility of drugs (see pg. 13, abstract; pg. 20, left col. and pg. 24, left col.). However, for improved solubility of the drug, Vervaet et al. teach the addition of both HFA propellant and co-solvents (see abstract, pg. 13). Importantly, Vervaet teaches that due to the fact that surfactant solubility and drug solubility are heavily reliant on the ability to form dipole-dipole interactions between the solute and the liquid propellant, small amounts of competing dipolar molecules such as water can cause precipitation and thus strict control of water is required for co-solvents free HFA formulations (see pg. 19, left col., and right col., paragraph 2).

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious to formulate the composition of Gupta et al. in an MDI formulation and add propellants such as HFA 134a and HFA 227 along with ethanol and water since Gupta et al. teach that his composition can be formulated as an MDI and Vervaet et al. teach that HFA are the new alternatives to CFC propellants. Moreover, one of ordinary skill in the art would have found it obvious to add water in small amounts and optimize the concentration of the propellants since Vervaet et al. teach that water needs to be strictly controlled along with the amount of propellants for solubility purposes. Given the teachings of Gupta, Jenkins, Lucas, and Vervaet, one of ordinary skill in the art would have found it obvious to add propellant, water, and ethanol with the reasonable expectation of providing a composition that is effectively administered in MDIs and a composition that is highly stable.

While the exact dosages of the ingredients are not disclosed by Vervaet et al., it is generally noted that differences in concentration do not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or dosage is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Given that applicant did not point out the criticality of specific ranges or dosages of the invention, it is concluded that the normal desire of scientists or artisans to improve upon what is already generally known would provide the motivation to determine where in a disclosed set of ranges is the optimum dosage range.

Claims 43-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gupta et al. (U.S. 2002/0006933 A1, previously cited) in view of Jenkins et al. (Pharmacokinetics: Drug, Absorption, Distribution, and Elimination, 1998, Chapter 3, pgs. 1-51.) and in further view of Lucas et al. (Pharmaceutical Research 1999, Vol. 16, No. 10, pgs. 1643-1647, previously cited) as applied to 1-2, 4-10, 13-18, 21-28, and 42 above and in further view of Pierre et al. (Annals of Allergy, Asthma and Immunology, April 1999, Vol. 82, No. 4, pgs. 377-382, abstract, previously submitted).

The Gupta et al. reference is as discussed above and incorporated by reference herein. However, Gupta does not particularly teach specific types of dry powder inhaler devices.

Pierre et al. teach the use of both propellant driven inhalers as well as breath actuated devices in treating asthma (see abstract). Importantly, Pierre et al. demonstrated that no significant differences existed in the potency and delivery system of the two devices (see abstract).

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious to formulate the composition of Gupta et al. as either an active inhaler or a breath actuated inhaler depending on the desired type of product and/or patient's preferences and ease of compliance. Given the teachings of Gupta, Jenkins, Lucas, and Pierre, one of ordinary skill in the art would have found it obvious to select either an active inhaler or a breath actuated inhaler for the administration of the composition of Gupta et al. in the treatment of sexual dysfunction with the reasonable expectation of providing a composition that is effectively administered in MDIs and a composition that is highly efficient in its delivery system.

Claims 45-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gupta et al. (U.S. 2002/0006933 A1, previously cited) in view of Jenkins et al. (Pharmacokinetics: Drug, Absorption, Distribution, and Elimination, 1998, Chapter 3, pgs. 1-51.) and in further view of Lucas et al. (Pharmaceutical Research 1999, Vol. 16, No. 10, pgs. 1643-1647, previously cited) as applied to 1-2, 4-10, 13-

18, 21-28, and 42 above and in further view of Snow (U.S. 2002/0134382 A1, previously cited).

The Gupta et al. reference is as discussed above and incorporated by reference herein. However, Gupta does not particularly teach the use of a blister in the dry powder composition.

Snow teaches a medicament container configured to improve entrainment of the medicament in the air and to improve deposition of the medicament in the lungs (see abstract). Snow further teaches that several types of inhalation of devices exist and dry powder inhalers are one type of inhalation devices (see pg. 1, paragraph 0008). Snow further teaches that dry powder medicaments often relies on providing a package containing multiple doses of medicament wherein each is contained in a sealed blister (instant claim 45; see pg. 1, paragraph 0012). In fact, Snow teaches that the instant invention can comprise a blister type pack wherein the upper layer and bottom layer of the container is formed by a generally planar piece of material that may be readily punctured (see pg. 4, paragraph 0063 and pg. 5, paragraph 0076). Preferred embodiments include the upper layer formed by a piece of foil forming a disk and such use of foil for blister packs is well known in the art and several types of foil are readily available (instant claim 46; see pg. 4, paragraph 0063). Moreover, Snow teaches that the lower layer can be formed of materials which are more durable than foil and be

made of materials such as polypropylene that are compatible with the medicament being used (see pg. 5, paragraph 0077).

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious to formulate the composition of Gupta et al. as a blister pack since it is well-known in the art to formulate dry powder inhalers in blister pack and given that Snow teaches dry powder medications in foil blister packs for easy penetration by lancets. Moreover, one of ordinary skill in the art would have found it obvious to further formulate the disk with propylene containing layers since Snow teaches that such layers are compatible with the medicament. Given the teachings of Gupta, Jenkins, Lucas, and Snow, one of ordinary skill in the art would have found it obvious to formulate the composition of Gupta et al. in a sealed blister pack and further include propylene layer for compatibility purposes with the reasonable expectation of providing a composition that is properly sealed and a container that is easily accessible.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samira Jean-Louis whose telephone number is 571-270-3503. The examiner can normally be reached on 7:30-6 PM EST M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SAMIRA JEAN-LOUIS/

Examiner, Art Unit 1627

08/12/2011